AD_____

Award Number:
W81XWH-06-10787

TITLE: DIETARY SUPPLEMENT USE BY MILITARY PERSONNEL

PRINCIPAL INVESTIGATOR:

Maria P. Oria, Ph.D.

CONTRACTING ORGANIZATION:
The National Academy of Sciences
Washington, DC 20001

REPORT DATE:

December 2008

TYPE OF REPORT:

Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*



| 1. REPORT DATE *(DD-MM-YYYY)* | 2. REPORT TYPE | 3. DATES COVERED *(From - To)* |
|---|---|---|
| 01-12-2008 | Final Addendum | 30 May 2008 - 30 Nov 2008 |

**4. TITLE AND SUBTITLE**
Dietary Supplement Use by Military Personnel

**5a. CONTRACT NUMBER**

**5b. GRANT NUMBER**
W81XWH-06-1-0787

**5c. PROGRAM ELEMENT NUMBER**

**6. AUTHOR(S)**
Maria P. Oria, Ph.D.

**5d. PROJECT NUMBER**

**5e. TASK NUMBER**

**5f. WORK UNIT NUMBER**

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
The National Academy of Sciences
500 5th st NW
Washington DC 20001

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
USA Medical Research and Materiel CoCommand
504 Scott Street
Fort Detrick MD 21702-5012

**10. SPONSOR/MONITOR'S ACRONYM(S)**

**11. SPONSOR/MONITOR'S REPORT NUMBER(S)**

**12. DISTRIBUTION / AVAILABILITY STATEMENT**

**13. SUPPLEMENTARY NOTES**

**14. ABSTRACT**

An Institute of Medicine expert committee was convened to review the use of dietary supplements by military personnel and provide recommendations to the Department of defense about determining their safety The committee held a public workshop on February 12-13, 2007, in Washington, D.C., to gather results from military surveys on the use of dietary supplements, and current approaches and innovative ideas on monitoring adverse effects; this information was of primary consideration in the preparation of this report. The committee also reviewed the 2005 IOM report *Dietary Supplements: A Framework for Evaluating Safety* as a starting point for its deliberations. The committee considered the special demands facing military subpopulations that set them apart from the general population. The committee wrote a report with recommendations for an approach to management by military leadership of the use of dietary supplements and identifies general areas of research needs. The recommended approach applies to all branches of the military.

**15. SUBJECT TERMS**
**Dietary supplements; safety; military use; surveys; framework**

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
|---|---|---|---|---|---|
| a. REPORT UNCLASSIFIED U | b. ABSTRACT UNCLASSIFIED U | c. THIS PAGE UNCLASSIFIED U | UU | 8 | USAMRMC |
| | | | | | 19b. TELEPHONE NUMBER *(include area code)* |

**Table of Contents**

**Page**

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Food and Nutrition Board

February 20, 2009

USA Medical Research and Materiel Command
ATTN: Ms. Juanita Livingston
504 Scott Street
Fort Detrick MD 21702-5012

Re: Contract Number W81XWH-06-10787
Dietary Supplement Use By Military Personnel
Final Report

Dear Ms. Livingston:

I am pleased to submit the following final progress report on the above-referenced contract and task order for the period, September 1, 2006 through December 31, 2008.

**Activities during September 1, 2006 – December 31, 2006**

The initial period of this activity was devoted to solicitation of nominations and to formation of the committee. In addition, planning for the first committee meeting and public workshop was completed during this period.

In developing the slate, nominees, were selected to reflect the balance of specialized scientific expertise in the areas of Clinical Medicine, Dietetics, Nutritional Biochemistry, Nutritional Toxicology, Exercise Physiology/Physical Activity and Dietary Supplements, Botanicals and Infectious Disease, Dietary Supplements and Mental Performance, Safety Assessment of Dietary Supplements, and Epidemiology needed for this committee. Following standard procedures of the National Academies, the Institute of Medicine and National Research Council considered the committee composition and a provisional committee of 12 members was approved on November 1, 2006.

**Activities during January 1, 2007 – December 31, 2007**

The beginning part of this year was devoted to continuing the logistical planning and to the preparation of materials for the public workshop***Dietary Supplement Use by Military Personnel.*** In addition, the speakers were carefully briefed regarding the needs of the committee and the nature of this workshop and members were prepared for their role in the committee and were provided with background information related to the task. The workshop was held on February 12-13, 2007 in Washington, DC. Briefly, the workshop included sessions devoted to a general introduction of the committee's task and the problem at hand; description of the results from recent surveys on dietary supplement use by military personnel; and the current knowledge on approaches to manage the safety of dietary supplements.

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

500 Fifth Street, NW
Washington, DC 20001

Phone: 202 334 1732
Fax: 202 334 2316
E-mail: fnb@nas.edu
www.national-academies.org/iom/fnb

This first committee meeting was held on February 12 (morning) and February 14 and included the following activities:

- -committee members bias and conflict of interest discussion led by Susanne Stoiber, executive president of IOM
- -open session with representatives of the sponsoring agencies with the purpose of clarifying any questions related to the task.
- -closed session where the committee discussed the approach to answer the questions and future meetings.

Based on the information received at the workshop, it was decided to expand the expertise to include an additional expert on neurobehavior and mental functions. Dr. David Dinges from School of Medicine at the University of Pennsylvania joint the committee as a consultant because of his expertise on the effects of stress on mental functions and specifically sleep deprivation.

Following the meeting, the committee held 3 conference calls to follow up with the initial assignments and continue answering the questions in the statement of task. In addition, the chair of the committee and the IOM senior program officer met once to discuss the progress and potential concerns. Also, based on the results from the surveys during the workshop, the number of dietary supplements to review is currently larger than originally anticipated.

Time was then devoted to drafting some of the ideas that had been deliberated by the committee during the public workshop and the first committee meeting. There were also many post-meeting requests for additional information on various aspects of the surveys, so the workshop presenters were contacted and the information was obtained when available.

The second committee meeting was held on June 11-12, 2007 in Washington, DC and included the following activities:

- In depth review of the dietary supplements drafts
- Deliberations of the committee to answer other questions in the statement of task
- Public presentation by Andy Stergachis, Ph.D., R.Ph.,, Professor of Epidemiology and Adjunct Professor of Pharmacy, School of Public Health and Community Medicine, University of Washington. Dr. Stergachis presented to the committee perspectives on establishing an adverse event monitoring system that was based on experience from drug adverse event monitoring.
- Discussion about next steps, deadlines, and expectations for the next several months.

Following the meeting, communications continued via email and telephone calls to follow up with the initial assignments and continue answering the questions in the statement of task. In addition, the chair of the committee and the IOM senior program officer held phone calls to discuss the progress and potential concerns. The study director also met with FDA officers Dr. Gerald Del Pan and Dr. Vasilios Frankos to further discuss details about their activities to monitor adverse effects.

During this time, the major effort focused on preparing for a productive third committee meeting. In preparation for the meeting, the following activities took place:

- The selection of dietary supplements for review was completed.
  - Research was conducted on approaches to survey systems, monitoring systems, and on safety decision-making processes for dietary supplements were discussed.
  - Numerous communications took place with individual members to discuss these approaches.
  - Communications took place with workshop speakers to obtain additional information on various aspects of the military system.
  - Workshop papers were collected and consulted.
  - Various chapters of the report were drafted.
  - A complete first draft of the report was shared among committee members by the beginning of September.
  - Major recommendations were written during the last part of the quarter.

Additional funding was obtained from the Office of Dietary Supplements (National Institutes of Health) and the Food and Drug Administration. Additional funding was explored with USA Medical Research and Materiel Command.

The last part of the year was devoted to finalizing the recommendations and defining a roadmap (including a timeline) to finalize the report for external review. The third committee meeting was held on October 4-5 at the Keck building at 500 Fifth Street, N.W., Washington, DC. After the meeting numerous calls were scheduled throughout the quarter with a definite plan to reach consensus on the recommendations and language for the various chapters of the report. A final draft for external review was completed for committee members' approval and sign off, pending final editing. A professional copy editor was hired for this purpose and to perform the final edit of the report to conform to IOM style and format.

A slate of reviewers, with expertise on epidemiology, toxicology, nutrition, adverse event reporting and pharmacognosy were selected based on recommendations from the Committee on military Nutrition Research, Food and Nutrition Board Members, IOM staff and others.

**Activities during January 1, 2008 – December 31, 2008**

The response to external review was finalized and final sign off was obtained from the National Research Council review committee and the Committee on Dietary Supplement Use by Military Personnel. A prepublication copy was sent to all sponsors by the end of May, prior to public release of the report on June 10th.

A sponsor briefing was held on June 3rd at the Samueli Institute headquarters in Alexandria, VA. The following committee members attended the briefing and answered questions from the sponsors: M.R.C. Greenwood (Chair), Cheryl Anderson, John Erdman, Elizabeth Jeffery, and Esther Myers. IOM staff also attended the briefing. The report was well received and sponsors offered very positive comments regarding the value and feasibility of its recommendations as well as their potential for implementation.

A second briefing of the report was held during the annual meeting of the standing Committee on Military Nutrition Research on June 17. Sponsors attending this meeting reiterated the value of the report.

**Reportable Outcomes**

The final report titled *Dietary Supplement Use by Military Personnel* was published in early November.

I presented a summary of the report in the Health Promotion Readiness Track at the 11th Annual Force Health Protection Meeting in Albuquerque, New Mexico (August 8-15th). Dr. Rebecca Costello (Office of Dietary Supplements at the National Institutes of Health) and Dr. Joan Walter (The Samueli Institute) presented a description of their respective institutions, their work related to dietary supplements, and their perspective on the IOM report. Information about the report was also displayed at the meeting's exhibit hall booth of the Office of Dietary Supplements.

Also, as part of the dissemination activities, the staff participated in the 114th Annual meeting of the Association of Military Surgeons of the United States (AMSUS) on November 9-14. The dietary supplement report was exhibited along with many other IOM reports relevant to the military.

**IOM Staff**

**Maria P. Oria,** Study Director
**Shannon L. Wisham,** Research Associate (Until April 2008)
**Alice Vorosmarti,** Research Associate (From April 2008)
**Sandra Amamoo-Kakra,** Program Associate
**Hilary Ray,** Editor

**Conclusion**

An Institute of Medicine expert committee was convened to review the use of dietary supplements by military personnel and provide recommendations to the Department of defense about determining their safety The committee held a public workshop on February 12–13, 2007, in Washington, D.C., to gather results from military surveys on the use of dietary supplements, and current approaches and innovative ideas on monitoring adverse effects; this information was of primary consideration in the preparation of this report. The committee also reviewed the 2005 IOM report *Dietary Supplements: A Framework for Evaluating Safety* as a starting point for its deliberations. The committee considered the special demands facing military subpopulations that set them apart from the general population. The committee wrote a report with recommendations for an approach to management by military leadership of the use of dietary supplements and identifies general areas of research needs. The recommended approach applies to all branches of the military.

## References

Institute of Medicine. 2008. Use of Dietary Supplements by Military Personnel. Washington, DC: The National Academies Press.

Please feel free to contact me if you have any questions (202.334.2321 or moria@nas.edu).

Sincerely,

Maria P. Oria, Ph.D.
Study Director, Committee on Dietary Supplement Use by Military Personnel
Food and Nutrition Board